



APPLICATION FOR UNITED STATES PATENT

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Invention: METHOD AND APPARATUS FOR FORMING A CENTERED
BORE FOR THE FEMORAL STEM OF A HIP PROSTHESIS

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SPECIFICATION



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METHOD AND APPARATUS
FOR FORMING A CENTERED BORE FOR THE
FEMORAL STEM OF A HIP PROSTHESIS

BACKGROUND OF THE INVENTION

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1. Field of the Invention:

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The present invention relates to the implantation of prosthesis devices, and, more particularly, to the preparation of the femur for the implantation of a prosthetic hip replacement device therein by the formation of a centered bore in the intramedullary canal of the femur.

2. Related Art:

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Bone diseases and injuries to joints often make it necessary or desirable to replace a natural joint with an artificial prosthesis. One such replacement involves the fixation of a stem of a prosthetic hip joint within the femur. The femur contains an intramedullary canal filled with cancellous bone within which the stem of the prosthesis can be implanted. With such implantation, it is desirable to fix the stem to the femur centrally within the intramedullary canal.

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In preparing the femur to accept the prosthetic device, the femoral head is removed to expose the intramedullary canal. A bore is formed in the canal and the femoral stem of the prosthesis is inserted into the canal and fixed to the femur by an interference fit, or by cement fixation.

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When the prosthesis is joined with the femur, it is ideally centered within the intramedullary canal so that there is no undue pressure on the cortical bone which might cause pain to the recipient of the prosthesis and even result in bone penetration. The centering of the femoral stem of a prosthesis has been addressed. For example, Techmedia, a company located in Camarillo,

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California, has proposed using a small plastic centering device attached to the tip of the femoral stem. However, the attachment of such a device to a femoral stem creates several associated problems.

5 For example, such plastic attachments increase the overall cost of the prosthesis. Additionally, the attachment of a plastic centering device to a metal femoral stem often causes some weakening of the stem, thus increasing the chance of deterioration of

10 the fixation of the prosthesis to the femur and the likelihood that the prosthesis will need replacement.

SUMMARY OF THE INVENTION

An object of the present invention is to overcome the problems noted above. The invention centers the femoral stem of a prosthesis within the intramedullary canal in a patient's femur so that no undue pressure is placed on the cortical bone which could cause pain to the patient and even result in cortical bone penetration.

According to the present invention, a device for preparing the femur for prosthesis implant is formed in assorted sizes so as to fit the intramedullary canal of any patient. The device is inserted into the intramedullary canal. The device includes an elongated rod having fins joined to the rod's distal end, the fins projecting outwardly from the rod and being disposed at 180° to one another relative to the rod. As the device is inserted into the canal, it first is oriented with the fins extending in an anterior-posterior relationship to the femur, and with the fins engaging the cortical bone, whereby the device creates a bore which is centered, front to back, relative to intramedullary canal. The device is then removed, rotated ninety

degrees, and reinserted in the bore, thus centering the device in its medial to lateral relationship with the femur. The bore that is thus formed is centered at a depth established by length of rod 5 inserted into the intramedullary canal. When the femoral stem of the prosthesis subsequently is implanted within the bore, it is properly positioned.

In accordance with a further object of the 10 invention, a method is provided for forming a cavity in a femur for receiving a prosthetic device. As a preliminary step, the femoral head is removed so as to expose the femur's intramedullary canal. The method then includes the step of selecting a device 15 of the type described above that will fit within the intramedullary canal such that its fins will engage the cortical bone of the patient. The device is then inserted, withdrawn and reinserted into the intramedullary canal in the manner previously 20 discussed so as to create a bore which is centrally positioned relative to the femur's cortical bone. Once the bore is so formed, the femoral stem of the 25 prosthetic device may be attached to the bone in a manner so that the prosthesis is centered with respect to the bone. Typically, the bore will require enlargement prior to attachment of the prosthetic device. This may be done by compacting the 30 walls of the bore using a device such as that disclosed, for example, in U.S. Patent Application Serial No. 08/309,592, entitled "Instrument for Proximal Femoral Compaction Broaching", the subject matter of which is incorporated herein by reference.

Other objects, features and 35 characteristics of the present invention, as well as the function of the related elements of the structure, and the economies of manufacture, will become more apparent upon consideration of the

following detailed description and the appended claims, with reference to the accompanying drawings, all of which form a part of this specification.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Figs. 1(a) and 1(b) are, respectively, segmented front and side elevational views of a device according to the present invention;

10 Fig. 2 is a cross-sectional view of a portion of a femur in which a prosthetic device is to be fit;

15 Figs. 3 and 4 illustrate a process of forming a bore within the intramedullary canal of the femur shown in Fig. 2;

20 Fig. 5 depicts the bore formed by the process illustrated in Figs. 3 and 4;

25 Fig. 6 shows the insertion of a first serial compactor into the bore for shaping the femur to receive the prosthetic device; and

30 Fig. 7 illustrates the prosthetic device attached to the femur.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY EMBODIMENT

35 Referring to Figs. 1(a) and 1(b), the device used to form a bore in an intramedullary canal of a femur is generally shown at 10. The device is substantially T-shaped and includes a handle 12 joined to an elongated rod 14, preferably of circular cross section. At the distal end 16 of rod 14, fins 18 are formed. Fins 18 are substantially semi-elliptical in shape for the reason which will be described hereafter. They are positioned 180° apart and project outwardly from the rod.

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5 *permit* The handle 12 is of sufficient length to provide the surgeon with enough leverage to insert the rod 14 into the intramedullary canal and withdraw it. Furthermore, the handle facilitates manipulation and orientation of device 10.

10 Preferably, rod 14 is at least 30 cm long, and is made of rigid metal provided with graduated markings along its length. The markings 20 permit the surgeon to determine how far rod 14 has been inserted into the intramedullary canal thereby permitting bores of different length to be formed. Fins 18 are formed integrally with rod 14 so as to avoid fracture or separation. A span d (Fig. 1(a)) encompassed by the fins is dimensioned so that the outer surfaces of the fins will engage the interior wall of cortical bone within the femur. Typically, the span will be about twelve mm. It will be understood, however, that the device 10 will be produced in assorted sizes, for example, with spans varying about one or two mm between sizes, so as to accommodate use within femurs of different dimensions. Ideally, device 10 will be available in ten to twenty different sizes in a set of instruments.

25 As can be appreciated from Fig. 1(b), fins 18 have planar surfaces which typically are between one and two mm apart. This is substantially less than the diameter of rod 14, which nominally has a five mm diameter.

30 Fig. 2 illustrates an end of a femur, shown generally at 21, to which a prosthetic device is to be attached. The first step in preparing femur 21 for implantation of the femoral stem of a prosthetic device is to expose the femur's proximal neck 23 and intramedullary canal 22 by removal of the femoral head. Cancellous bone is contained within the intramedullary canal. The anticipated

position of a femoral stem within such bone is denoted by dotted line 24,

5 In practice, utilizing a procedure such as x-ray, preliminary measurements are made of a patient's intramedullary canal diameter at a depth appropriate for implantation of the femoral stem. For the sake of example, Fig. 2 shows a measurement wherein the depth of the anticipated femoral stem is eleven cm, and the width of canal 22 is ten mm at that depth. These measurements inform the surgeon 10 as to the size of device 10 which is required.

The surgeon selects a device 10 having a ten mm span d. The rod 14 is then inserted into canal 22, as shown in Fig. 3, until the graduated 15 markings 20 show that it is eleven cm deep. As the rod is inserted, the fins 18 are oriented in the anterior-posterior plane of the femur. As the fins 18 approach the preestablished depth of eleven cm, they engage the interior wall of the femur's 20 cortical bone. This causes the rod 14 to be centered within the intramedullary canal. Rod 14 is then withdrawn. In this manner, rod 14 forms a bore 25 having compacted cancellous bone material along its wall and at the bottom of the bore. Because of 25 the rod's anterior-posterior orientation during insertion, the bore is centered front to back within the intramedullary canal. If the selected rod 14 is unable to reach the desired depth, i.e., eleven cm, a smaller device 10 is chosen to form the bore.

30 Fig. 4 illustrates the next step in the process. After rod 14 is removed from bore 25, the device is rotated ninety degrees and rod 14 is reinserted into bore 25 with fins 14 in medial to lateral orientation relative to the femur. Rod 14 35 again is displaced until it reaches the eleven cm marking 20. At that point fins 18 engage the

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cortical bone so that the rod again is centered within the intramedullary canal.

5 The bore 25 created by the above-described process is shown in Fig. 5. It is eleven cm deep, ~~has a diameter of ten mm~~, and is centered within intramedullary canal 22. Because of the fins' semi-elliptical shape, the rod 14 can be smoothly inserted and withdrawn from the femur.

10 As an alternative to the two-step insertion process just described, four fins 18, spaced at 90° intervals about rod 14, can be employed so that a centered bore is created by a single insertion and withdrawal of the rod.

15 Fig. 6 illustrates the use of a compacting device 26 to widen and shape bore 25 at the proximal end of femur 21. Compacting device 26 is a broach having the general configuration of the upper portion of the femoral stem of the prosthesis being implanted. As described in detail in the above-referenced Application Serial No. 08/309,592, the 20 broach further compacts the cancellous bone material found along the wall of bore 25, thus providing additional side wall support for the prosthesis. Several broaches of differing sizes may be used to 25 progressively enlarge and shape bore 25 at this location.

30 In Fig. 7, the bore has been enlarged to accommodate the femoral stem 29 of prosthetic device 30. Original bore 25 is shown by a dotted line. Reference number 28a illustrates the enlarged bore 35 formed by further compacting the cancellous bone material with devices having the general shape of the femoral stem. Dotted line 26a indicates the outline of the wall formed by compactor 26 (shown in Fig. 6) once the compactor is removed. In this manner, the entire cavity is formed to receive the femoral stem. The prosthesis then can be secured to

the femur by conventional cement or non-cement techniques.

5 If a cement restraint is desired for an implanted prosthesis and insufficient bone is available at the bottom of bore 25 for that purpose, additional bone material can be harvested from the amputated femoral head and packed down into the bottom center of the bore.

10 In the embodiments described, the fins 10 are formed integrally with the rod 14 from a single piece of metal stock. Alternatively, they could be detachably secured to the rod and made of metal or synthetic materials.

15 The handle 12 is illustrated in Fig. 1(a) as being fixed to rod 14. However, it also can be removable. In the latter case, with rod 14 inserted within the intramedullary canal and the handle removed, the rod can serve as a guideway for cannulated compactors to enlarge and shape bore 25.

20 While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but, on the contrary, 25 is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.